



## **MediciNova Announces Exploratory Interim Clinical Outcomes Data from Clinical Trial of MN-166 (ibudilast) in ALS Presented at the 27th International Symposium on ALS/MND in Dublin, Ireland**

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LA JOLLA, Calif., Dec. 09, 2016 (GLOBE NEWSWIRE) -- MediciNova, Inc., a biopharmaceutical company traded on the NASDAQ Global Market (NASDAQ:MNOV) and the JASDAQ Market of the Tokyo Stock Exchange (Code Number: 4875), today announced that principal investigator Dr. Benjamin Rix Brooks, Director, Carolinas HealthCare System's Neuromuscular/ALS-MDA Center, today presented exploratory interim data from MediciNova's ongoing clinical trial of MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS) at the 27th International Symposium on ALS/MND (amyotrophic lateral sclerosis/motor neurone disease) in Dublin, Ireland.

The exploratory interim analysis includes a total of 26 subjects who completed the 6-month open-label extension period of the study which followed the 6-month double-blind treatment period. All subjects received MN-166 (ibudilast) during the 6-month open-label extension period and then stopped taking MN-166 (ibudilast) at the end of Month 12 which was the end of the 6-month open-label extension period. The exploratory interim analysis compares clinical outcomes for these subjects at two time points, Month 12 (the end of the 6-month open-label extension period) vs. Month 12 + 2 weeks (after 2 weeks without MN-166), to determine the effect of stopping MN-166 (ibudilast) treatment on clinical outcomes.

Major highlights from the presentation, "*Adaptive Design Single Centre Phosphodiesterase Type 4 (PDE-4) Inhibitor – Ibudilast (MN-166) Phase 1b/2a Clinical Trial [NCT02238626] for Amyotrophic Lateral Sclerosis (ALS) Patients [1] Not Requiring Non-Invasive Ventilation (no-NIV) up to 5 years and [2] Requiring Non-Invasive Ventilation (NIV) up to 10 years from Disease Onset*" include the following:

1 There were statistically significant decreases in muscle strength 2 weeks after stopping MN-166 (ibudilast) for

- Hip Flexion, a measure of hip muscle strength ( $p=0.001$ )
- Leg Flexion, a measure of leg muscle strength ( $p=0.049$ )
- Neck Flexion, a measure of neck muscle strength ( $p=0.004$ );

2 There was a decrease (not statistically significant) 2 weeks after stopping MN-166 (ibudilast) in

- the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R-Total) score, a measure of functional impairment
- Vital Capacity (VC), a measure of respiratory function; and

3 MN-166 (ibudilast) was well tolerated

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased with the encouraging interim data from this exploratory analysis, which may indicate that the clinical symptoms of ALS patients deteriorate shortly after stopping treatment with MN-166. We believe MN-166 could potentially offer a substantial clinical benefit in the treatment of ALS. We look forward to the completion of the six-month double-blind portion of the study next year."

### **About the ALS Trial**

MediciNova, in collaboration with Dr. Benjamin Rix Brooks, Director, Carolinas HealthCare System's Neuromuscular/ALS-MDA Center, is currently evaluating MN-166 (ibudilast) in both early and advanced stage ALS patients. This ongoing trial is a randomized, double-blind, placebo-controlled study which includes a six-month treatment period followed by a six-month open-label extension. The study is evaluating several efficacy endpoints including functional activity (ALSFRS-R), respiratory function and muscle strength in subjects with ALS. The study is configured to enroll up to 60 ALS patients without NIV (Non-Invasive Ventilator) and up to 60 ALS patients with NIV.

### **About ALS**

Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. The nerves lose the ability to trigger specific muscles, which causes the muscles to become weak. As a result, ALS affects voluntary movement and patients in the later stages of the disease may become totally paralyzed. Life expectancy of an ALS patient is usually 2-5 years. According to the ALS Association, there are approximately 20,000 ALS patients in the U.S. and approximately 6,000 people in the U.S. are diagnosed with ALS each year. Riluzole is the only pharmaceutical treatment approved for ALS, but it has limited efficacy.

### **About MN-166 (ibudilast)**

MN-166 (ibudilast) has been marketed in Japan and Korea since 1989 to treat post-stroke complications and bronchial asthma. MediciNova is developing MN-166 for progressive MS and other neurological conditions such as ALS and substance abuse/addiction. MN-166 (ibudilast) is a first-in-class, orally bioavailable, small molecule phosphodiesterase (PDE) -4 and -10 inhibitor and a macrophage migration inhibitory factor (MIF) inhibitor that suppresses pro-inflammatory cytokines and promotes neurotrophic factors. It attenuates activated glia cells, which play a major role in certain neurological conditions. Ibudilast's anti-neuroinflammatory and neuroprotective actions have been demonstrated in preclinical and clinical study results and provide the rationale for its therapeutic utility in neurodegenerative diseases (e.g., progressive MS and ALS), substance abuse/addiction and chronic neuropathic pain. MediciNova has a portfolio of patents which cover the use of MN-166 (ibudilast) to treat various diseases including progressive MS, ALS, and drug addiction.

## About MediciNova

MediciNova, Inc. is a publicly-traded biopharmaceutical company founded upon acquiring and developing novel, small-molecule therapeutics for the treatment of diseases with unmet medical needs with a commercial focus on the U.S. market. MediciNova's current strategy is to focus on MN-166 (ibudilast) for neurological disorders such as progressive MS, ALS and substance dependence (e.g. alcohol use disorder, methamphetamine dependence, opioid dependence) and MN-001 (tipelukast) for fibrotic diseases such as nonalcoholic steatohepatitis (NASH) and idiopathic pulmonary fibrosis (IPF). MediciNova's pipeline also includes MN-221 (bedoradrine) for the treatment of acute exacerbations of asthma and MN-029 (denibulin) for solid tumor cancers. MediciNova is engaged in strategic partnering and other potential funding discussions to support further development of its programs. For more information on MediciNova, Inc., please visit [www.medicinova.com](http://www.medicinova.com).

*Statements in this press release that are not historical in nature constitute forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements regarding the future development and efficacy of MN-166, MN-221, MN-001, and MN-029. These forward-looking statements may be preceded by, followed by or otherwise include the words "believes," "expects," "anticipates," "intends," "estimates," "projects," "can," "could," "may," "will," "would," "considering," "planning" or similar expressions. These forward-looking statements involve a number of risks and uncertainties that may cause actual results or events to differ materially from those expressed or implied by such forward-looking statements. Factors that may cause actual results or events to differ materially from those expressed or implied by these forward-looking statements include, but are not limited to, risks of obtaining future partner or grant funding for development of MN-166, MN-221, MN-001, and MN-029 and risks of raising sufficient capital when needed to fund MediciNova's operations and contribution to clinical development, risks and uncertainties inherent in clinical trials, including the potential cost, expected timing and risks associated with clinical trials designed to meet FDA guidance and the viability of further development considering these factors, product development and commercialization risks, the uncertainty of whether the results of clinical trials will be predictive of results in later stages of product development, the risk of delays or failure to obtain or maintain regulatory approval, risks associated with the reliance on third parties to sponsor and fund clinical trials, risks regarding intellectual property rights in product candidates and the ability to defend and enforce such intellectual property rights, the risk of failure of the third parties upon whom MediciNova relies to conduct its clinical trials and manufacture its product candidates to perform as expected, the risk of increased cost and delays due to delays in the commencement, enrollment, completion or analysis of clinical trials or significant issues regarding the adequacy of clinical trial designs or the execution of clinical trials, and the timing of expected filings with the regulatory authorities, MediciNova's collaborations with third parties, the availability of funds to complete product development plans and MediciNova's ability to obtain third party funding for programs and raise sufficient capital when needed, and the other risks and uncertainties described in MediciNova's filings with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2015 and its subsequent periodic reports on Forms 10-Q and 8-K. Undue reliance should not be placed on these forward-looking statements, which speak only as of the date hereof. MediciNova disclaims any intent or obligation to revise or update these forward-looking statements.*

### INVESTOR CONTACT:

Geoff O'Brien  
Vice President  
MediciNova, Inc.  
[info@medicinova.com](mailto:info@medicinova.com)



MediciNova, Inc.